

chemwerth<sup>INC</sup>

January 23, 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 00N-1669

Dear Sirs:

We are interested in participating in the FDA's pilot program for electronic filing of Form 2656, Registration of Drug Establishment and Form 2657, Drug Product Listings.

Participants name: Chemwerth Inc.  
1764 Litchfield Turnpike  
Woodbridge, CT 06525  
(203) 387-7794  
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We are in a unique situation as we are the exclusive agent for approximately thirty foreign manufacturers and have approximately fifty API drug products listed for human and veterinary use. We are responsible for registering the establishment and drug listing the products. We represent manufacturers in Spain, India, Germany, and China. Due to governing changes in China, our manufacturers frequently make changes to their name, address, or manufacturing sites, all of which requires resubmissions to the FDA.

One 'comment' we have is that we are not sure when the 2657's we have submitted, have been completely processed. For instance, in late December and early January we submitted 2657's for eight products and at this juncture, are not really sure if everything has been processed and we should use the new labeling. The only time we hear from the FDA is when there is a deficiency. It would be nice to be able to go online to verify the drug product listing is updated.

We hope you will consider our request to participate and look forward to hearing from you.

Very truly yours,

  
Fawn S. Katynski

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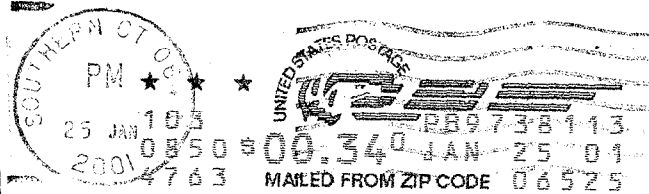
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